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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,202	06/16/2006	David John Hampson	34141-US-PCT	2206

1095 7590 10/01/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,202	HAMPSON ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-9,11,13-18,20-24 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,6-9,11,13-18,20-24 and 27-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 27-30, and claim 24 (in part), drawn to polypeptides, and fragments and homologues thereof.

Group II, claim(s) 2, 6, 7, and 15, and claim 24 (in part), drawn to polynucleotides encoding the polypeptides, and kits comprising the polynucleotides.

Group III, claim(s) 8, 9, and 17, and claim 24 (in part), drawn to antibodies specific for the polypeptides, and kits comprising the same.

Group IV, claim(s) 11, drawn to a method of screening a sample for Brachyspira species using the polynucleotides.

Group V, claim(s) 13, drawn to a method of screening a sample for the polypeptide using the antibodies.

Group VI, claim(s) 14, drawn to a method of screening a sample for the antibodies using the polypeptides.

Group VII, claim(s) 18, 20, and 23 (in part), drawn to a therapeutic method of using the polypeptides to treat a disease.

Group VIII, claim(s) 18, 20, and 23 (in part), drawn to a therapeutic method of using the polynucleotides to treat a disease.

Group IX, claim(s) 21 and 22 (in part), drawn to a method of using the polynucleotides to immunize against a disease.

Group X, claim(s) 21 and 22 (in part), drawn to a method of using the polypeptides to immunize against a disease.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no significant structural feature in common among the claimed products of Groups I-III. The products exhibit materially different activities and undergo materially different biochemical reactions in vivo. The methods of Groups IV-VI lack the same or corresponding special technical feature because of the materially different reagents involved therein, and because of the materially different results produced by each screening method. The screening methods of Groups IV-VI lack the same or corresponding special technical feature with respect to the in vivo methods of Groups VII-X, because of the materially different method steps recited in the claims, and because of the materially different results produced by each method. The therapeutic methods of Groups VII and VIII lack the same or corresponding special technical feature with respect to the immunization methods of Groups IX and X, because of the materially different results produced by each method. Treating a disease is materially different than preventing a disease by immunization. The methods of Groups VII and X lack the same or corresponding special technical feature with respect to the methods of Groups VIII and IX, because there is no significant structural feature in common between the polypeptides of former and the polynucleotides of the latter, and because the polypeptides and polynucleotides will undergo materially different biochemical reactions in

vivo. In addition, the X references identified in the International Search Report are further evidence that the invention as claimed lacks the same or corresponding special technical feature.

If Applicants elect the invention of Group I, they may also elect one of Groups VI, VII, or X to be examined therewith. If Applicants elect the invention of Group II, they may also elect one of Groups IV, VIII, and IX to be examined therewith. If Applicants elect the invention of Group III, the invention of Group V will be examined therewith. See 37 CFR 1.475(b)(2). However, multiple patentably distinct methods of using a product do not necessarily satisfy the requirements of unity of invention, and will not all be examined together with the elected product. See 37 CFR 1.475(c) and (d).

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

With respect to Groups I, VI, VII, and X, the species are the polypeptides, fragments thereof, and homologues thereof, for SEQ ID NOS:2, 4-6, and 8-22. With respect to Groups II, IV, VII, and IX, the species are the polynucleotides encoding the polypeptides of SEQ ID NOS:2, 4-6, and 8-22, or having SEQ ID NO:1. With respect to Groups III and V, the species are antibodies specific for the polypeptides of SEQ ID NOS:2, 4-6, and 8-22. All claims are generic to the species set forth above.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are patentably distinct from one another

and lack the same or corresponding special technical feature because of their materially different sequences and structures. Each species will require a separate sequence and/or structure search, which constitutes an undue examination burden on the Office. In addition, the X references identified in the International Search Report are further evidence that the claimed species lack the same or corresponding special technical feature.

Applicant is required, in reply to this action, to elect a single species (i.e. a single polypeptide SEQ ID NO, a polynucleotide encoding a single polypeptide SEQ ID NO or having SEQ ID NO:1, or an antibody which binds to a single polypeptide SEQ ID NO) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

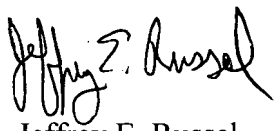
specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
September 17, 2007